

Surrogate biomarkers for monitoring healthcare quality for chronic diseases such as diabetes care

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ABSTRACT

Some laboratory tests or biomarkers are used as surrogate outcomes for health care effectiveness. HbA1c is defined as a surrogate biomarker since HbA1c values have been approved to be used in predictions of clinically important complications of diabetes mellitus. With the advance of information technology (IT) the real life data are aggregating as electronic health records (EHRs). About 70-85% of individuals admitted to hospitals have laboratory test results. As such, medical laboratories are the data centers in the hospitals. The test results can be used for assessment of health care delivered, especially for chronic diseases. This information provides insights of healthcare services, and can be used to enhance for individual and population well-being, research, and education. This article focuses on the importance of using laboratory tests results as outcome measures for specific population health status that are important in assessing the quality of health care services. The findings from our studies on the diabetic care quality is presented.

INTRODUCTION

Medical laboratories are one of the key players in the provision of healthcare, and responsible for healthcare quality. In order to create value-based health care, population-level outcomes and cost-effectiveness should be measured as well at the patient-level (1). The test results from the electronic health records can be used for getting information about population-level healthcare quality, especially for chronic diseases. In this context, laboratory professionals can present some valuable information about the quality of care to the health policy makers, since 70-85% of individuals admitted to a hospital have laboratory tests (2).

It is suggested that quality of care can be assessed according to the conceptualized frameworks suggested by Donabedian and the World Health Organization, and randomized controlled trials (RCTs) are suggested as the best model for assessment. However, RCTs of diagnostic procedures are not common because of the challenges in design and implementation (3-9). Electronic health records are providing new opportunities with high data collection capacity and can be used for assessment of the population status with specific disease according to the surrogate outcome measures such as HbA1c for diabetes

monitoring. Although the information obtained from the real life data is not enough for determination of the actual status, it can provide insights into further structured outcome studies. The data can be used by policy makers, especially in countries where no outcome assessments have been performed at the patient and/or population level. Laboratory professionals working in hospitals should have sufficient knowledge and skills in data management for extracting meaningful information from patients' test results besides their core professional knowledge. The objectives of this paper are to emphasize roles of medical laboratory professionals in the value-based health care model, present the examples on diabetes care quality, and to point out what competencies should be gained by laboratory professionals.

HEALTH CARE QUALITY MEASURES, OUTCOMES AND VALUE-BASED HEALTH CARE

Quality measures have been used in order to assess and compare the healthcare quality of an organization, quality of health care delivery services, and population health quality (3). The performance of health care is assessed by outcome measures. The "value-based health care-VBHC"

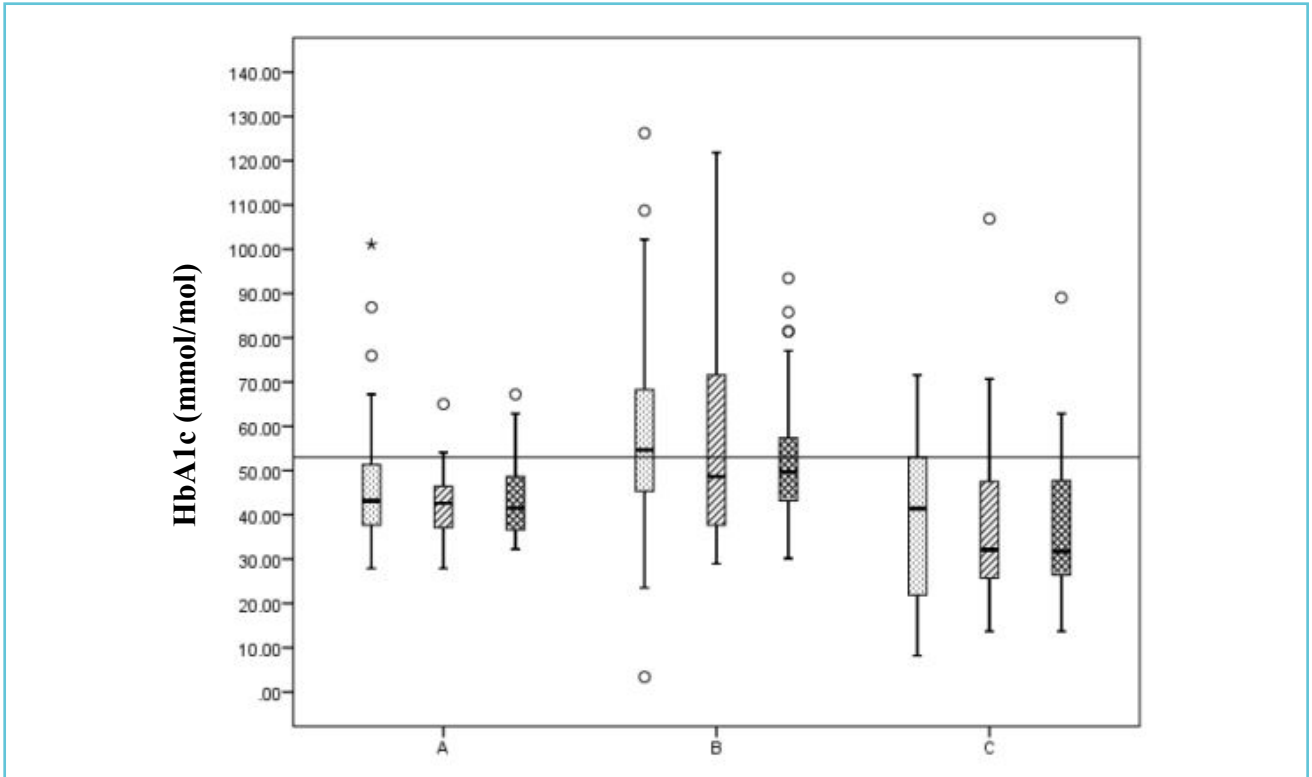
Table 1 Percentages of patients who have test values outside the HbA1c targets at the beginning and after six months

| Hospital | Poor controlled diabetics (%) | |
|------------|-------------------------------|----------|
| | 0. month | 6. month |
| Hospital A | 19 | 14 |
| Hospital B | 53 | 39 |
| Hospital C | 52 | 22 |

Data from our 6-month cohort study of 3 hospitals in different regions in Turkey (11).

Targets: HbA1c <53 mmol/mol (7%) (American Diabetes Association. Standards of medical care in diabetes, 2004).

Figure 1 Six month-cohort study on diabetic populations of three hospitals from three different regions of Turkey (2003-2004)



Hospital A is in the Western Part of Turkey (n=48), Hospital B in the South Eastern Part (n=145), and Hospital C is in the Southern (n=23). A and B are university hospitals, C is a private hospital.

All patient results were collected together with the evidence of quality assurance results of the laboratories.

model that is implemented in the US aims to increase the value that is provided from healthcare services available for a population (1). A report prepared according to the laboratory test results for specific disease population extracted from EHRs can provide an overall look about all the key supporting elements of the VBHC model.

ELECTRONIC HEALTH RECORDS, BIG DATA, POPULATION HEALTHCARE QUALITY

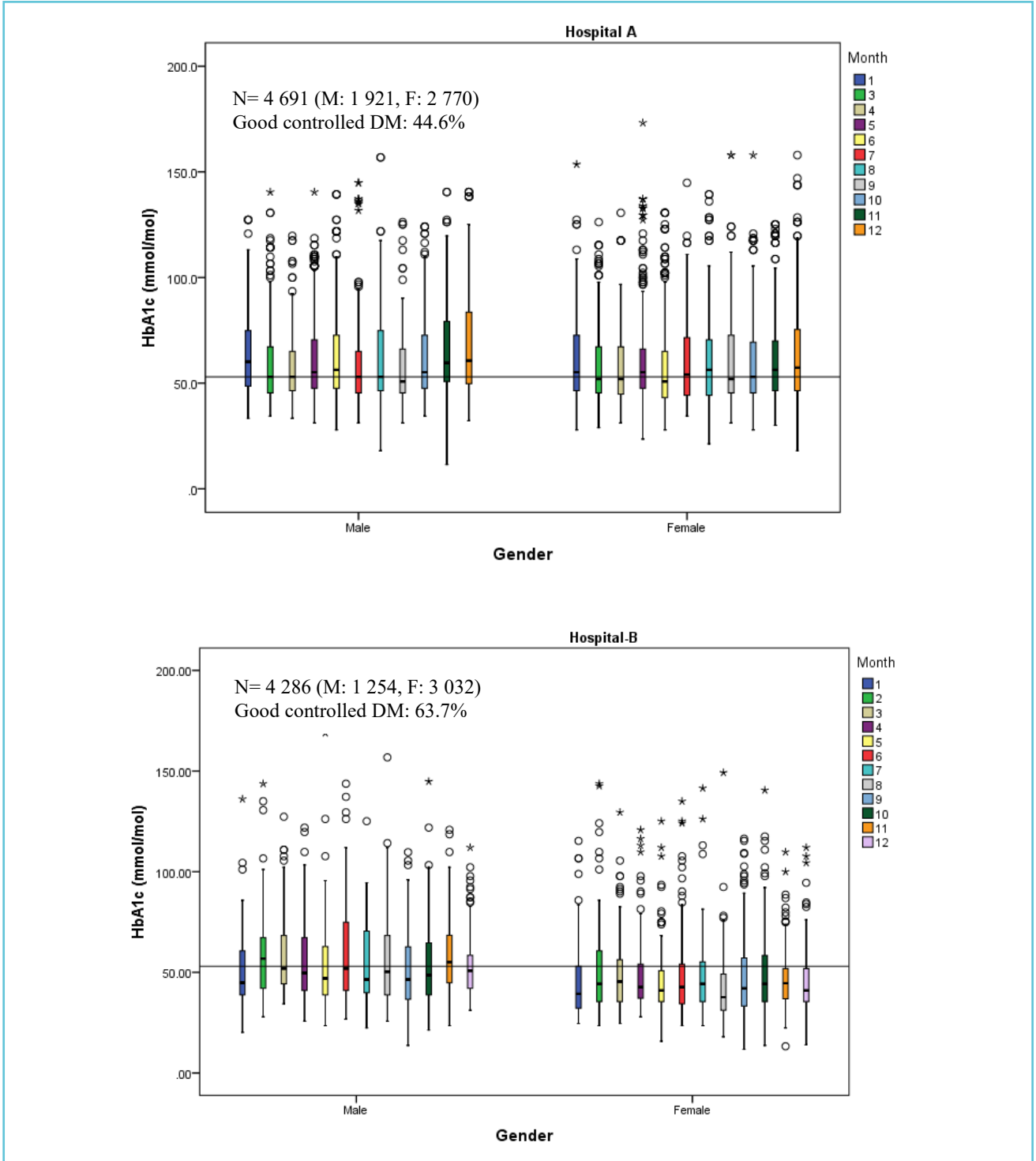
The EHRs are being recognized as an important tool for research as well as clinical care. The main objective should be to learn data mining techniques for extracting meaningful information from database obtained from the EHRs. Some countries have been establishing systems for enhancing the data mining capacities of relevant

organizations (4,5). The laboratory professionals with their data mining knowledge complemented with their core professional knowledge should be part of the data management teams at the hospitals along with epidemiologists and data scientists. They provide meaningful information from test results as a basis for tracking chronic diseases and insights into public health trends, and can aid the management of public healthcare policies (6,7).

DIABETES CARE QUALITY, HbA1c AND BIG DATA

Quality indicators for several diseases, for example, diabetes care quality, are being defined by government organizations and by scientific societies (8,9). Most of quality measurement in

Figure 2 Monthly HbA1c distributions of diabetics in 2017 from data collected in two hospitals in Denizli, Turkey



A is a university hospital, B is a private hospital.

Target for HbA1c: 53 mmol/L (7.0%).

All patient results were collected together with the evidence of quality assurance results of the laboratories.

diabetes mainly includes measures of process and intermediate outcomes, such as HbA1c as surrogate biomarker (10). Laboratory test results can be treated as part of indicative data and the findings from data mining can provide meaningful knowledge to the policy makers at national and individual levels.

DIABETIC CARE QUALITY TRACKING FOCUSING ON THE HbA1c LEVELS OF PATIENTS WITH DIABETES MELLITUS

The HbA1c values of diabetics admitted to the hospitals were collected for 40 years together with the evidence for the analytical quality assurance. In the first 12 years, there were no electronic health records. The test results of diabetics were recorded on their “diabetes test follow-up cards”. Our laboratory collected the results of glucose, HbA1c, and lipids tests and estimated the percentages of poorly controlled diabetics (1982-1994) and 93% of diabetics had HbA1c values higher 7.0% (53 mmol/mol).

Furthermore, HbA1c results of diabetics admitted to the Center of the Turkish Diabetes Society in Denizli between 1999-2003 were also collected and 53% of the patients had HbA1c values higher than 7.0% (53 mmol/mol).

The HbA1c distributions established from our research studies (2003-2005) and the distributions obtained from data extracted from the LISs (2017) are seen in the Figures 1 and 2, respectively (11,12). The percentages of patients that have values outside the targets at the beginning and the 6th month can be seen in the Table 1 extracted from our cohort study (11). All patient results were collected together with the evidence of analytical quality assurance results of the laboratories.

CONCLUSION

Observations and findings from our studies have shown that laboratory professionals should be

part of the data management team in health care organizations along with epidemiologists, statisticians, data scientists, and professionals from relevant disciplines. Laboratory professionals are one of the key players in health care services. They should be aware of the laboratory's value in improving the health of the population, not only the health of a single patient. The key issue is to realize what future challenges will be and what skills should be gained in order to cope with these challenges. Additional skills may be acquired to use relevant information technology and data mining methods in order to be part of the multidisciplinary teams.

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